

COMPANY
NAME
ADDRESS LINE 1
ADDRESS LINE 2
ZIP CODE CITY
COUNTRY

Hamburg, January 2021

Important safety information: Field safety corrective action on a medical device

Reference: FSCA MMS2 2021-01.01

From

WEINMANN Emergency Medical Technology GmbH + Co. KG

Addressee

Users and operators, as well as specialist dealers and service partners

Medical devices concerned (trade name)

MEDUMAT Standard² emergency and transport ventilator; the serial numbers of devices affected can be found in the appended table

Dear customers,

Quality and safety are our top priority, which is why we wish to act in a consistent and transparent manner as usual and, in the context of your obligation to co-operate under medical devices legislation, ask you to implement this corrective action so that users can continue to use our products on patients safely.

1. Description of problem

In the course of our regular quality controls in Production, we noticed that during a particular production period (see annex: serial numbers affected), one of the components of the pneumatic system of the MEDUMAT Standard² may deviate from original specifications during operation. This may lead to failure of the device.

Page 1 of 4

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WEINMANN Emergency
Medical Technology GmbH + Co. KG
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www.weinmann-emergency.com

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14 • 24558 Henstedt-Ulzburg
GERMANY

Business Management
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte

Registration Court
Hamburg Municipal Court
Dept. A # 115967
V.A.T. # DE288367727
WEEE Reg. # DE 47913245

Creditor ID
DE35ZZ00000353971

General Partner
WEINMANN Emergency
Management GmbH, Hamburg

Registration Court
Hamburg Municipal Court
Dept. B # 38144

Certified QM System meeting
EC directive 93/42/EEC, Annex II
(EN ISO 9001/EN ISO 13485)

Banking Connections

Deutsche Bank AG Hamburg
IBAN DE87 2007 0000 0646 9639 00
SWIFT DEUTDEHH

Hamburger Sparkasse AG
IBAN DE44 2005 0550 1032 2626 67
SWIFT HASPDEHHXXX

Commerzbank AG Hamburg
IBAN DE14 2004 0000 0632 0071 00
SWIFT COBADEHHXXX

2. Risk to the patient

This makes it more likely for the device to display a device malfunction (display turns yellow) during ventilation - either following a device start or in rare instances during ventilation. This means that the device is no longer ready for use.

3. Corrective action

The following corrective action must be performed:

- Repair the device pneumatic system

This corrective action is mandatory. The responsible authority has been informed of the procedure.

You can continue using your MEDUMAT Standard² until the corrective actions described have been performed. You and your staff should note, however, that you should always have an alternative ventilation option to hand as described in the instructions for use. You do not need to decommission the device.

Please perform all **actions by no later than March 29th, 2021**.

The paragraphs below describe the procedure you need to follow.

a. **If you are an owner/operator or user of MEDUMAT Standard² in Germany, proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions**, by no later than **February 5th, 2021**.
- Please ensure in your organization that this **safety information is brought to the attention** of all users of the above-mentioned product and of other people to be informed.
- Send all affected MEDUMAT Standard² devices to the following address, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed:

**Center for Production, Logistics, Service
WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, GERMANY**

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>
- If you have passed these products on to third parties, **please forward a copy of this information to them or notify us of their contact information**.

b. **If you are an owner/operator or user of MEDUMAT Standard² outside Germany, proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions**, by no later than **February 5th, 2021**.
- Please ensure in your organization that this **safety information is brought to the attention** of all users of the above-mentioned product and of other people to be informed.
- Send all MEDUMAT Standard² devices to your WEINMANN specialist dealer to have the above-mentioned actions carried out. As the reference, quote this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*.

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>
- If you have passed these products on to third parties, **please forward a copy of this information to them or notify us of their contact information**.

c. **If you are a WEINMANN specialist dealer, proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions**, by no later than **February 5th, 2021**.
- Please ensure in your organization that this **safety information** is brought to the attention of all users of the above-mentioned products and of other people to be informed.
- Please ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned products and of other people to be informed. **Please also pass this letter on to your customers for this purpose**.
- Send all affected MEDUMAT Standard² devices (for example customer, demonstration, lease and trade fair devices) to the following address, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed:

**Center for Production, Logistics, Service
WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, GERMANY**

OR

- Send all affected MEDUMAT Standard² devices to the **WEINMANN service partner responsible for you**, referencing this Field Safety Notice (FSN) *FSCA MMS2 2021-01.01*, for the above actions to be performed. For contact information, just go to our website at: <https://www.weinmann-emergency.com/contact/>

d. **If you are an authorized WEINMANN service partner for MEDUMAT Standard², proceed as follows:**

- Please use the attached report form to **confirm to us that this letter has been received or forwarded, regardless of other actions**, by no later than **February 5th, 2021**.
- Please ensure in your organization that this **safety information** is brought to the attention of all users of the above-mentioned products and of other people to be informed.
- Please ensure that this **safety information** is brought to the attention of all your customers for the above-mentioned products and of other people to be informed. **Please also pass this letter on to your customers for this purpose.**
- You will be receiving the document *Field Change Order FCO_FSCA_MMS2 2021-01.01* separately from this letter.
The *Field Change Order* explains the procedure for performing the remedial measures described above. Perform these remedial measures on all customer devices and on your own demonstration, lease and trade fair devices.
- Please perform all **actions by no later than March 29th, 2021** and **confirm that the actions have been performed** on the document described in *Field Change Order*.

Contact

If you have any questions or need support, please contact your local specialist dealer or contact us directly:

Phone: +49 40 88 18 96 – 122

E-mail: AfterSalesService@weinmann-emt.de.

Kind regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG



André Schulte
Managing Director



p.p. Dennis Horstmann
Authorized Signatory
Head of Supply Chain + Quality Management

Annexes

"Field safety notice received" report form
Table of serial numbers affected

Report to WEINMANN Emergency by February 5th, 2021

Regarding MEDUMAT Standard² safety information: Reference: FSCA MMS2 2021-01.01

Original letter sent to:

Insert ADDRESSEE FIELD as on page 1 of covering letter

Customer number

Company

Name

Address

Zip code City

COUNTRY

Please fill in this report form in full and return it by e-mail, fax or mail to:

e-mail: **AfterSalesService@weinmann-emt.de**

Fax: **+49 40 88 18 96 - 490**

WEINMANN Emergency Medical Technology GmbH + Co. KG

Technical Service

Frohbösestraße 12

22525 Hamburg, GERMANY

- I hereby confirm receipt of this letter and that I have read and understood its contents. This letter has been brought to the attention of all users of the product and of other people in my organization who need to be informed.

If the products have been passed on to third parties (applies to specialist dealers, for example), a copy of this information has been passed on to them.

Please complete in full in block capitals:

- Company/organization details are identical to those of the addressee above.

- Company/organization details differ from those of the addressee as follows:

Customer no.:

Company/organization + address:

- I am no longer in possession of the medical device:

- The device has been scrapped

- The new owner is (company + address)

Date, signature

Name (in block letters)

Position (in block letters)

e-mail address (in block letters)

Annex to FSCA MMS 2021-01.01
 MEDUMAT Standard² serial numbers affected

Table 1: Serial number of MEDUMAT Standard² (MMS2) devices affected

| | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|
| 1197 | 15284 | 15326 | 15375 | 15417 | 15458 | 15504 | 15550 |
| 1392 | 15285 | 15327 | 15376 | 15418 | 15459 | 15505 | 15551 |
| 5993 | 15286 | 15328 | 15377 | 15419 | 15460 | 15506 | 15552 |
| 7320 | 15287 | 15329 | 15378 | 15420 | 15461 | 15507 | 15553 |
| 7409 | 15288 | 15330 | 15379 | 15421 | 15462 | 15508 | 15554 |
| 7501 | 15289 | 15331 | 15380 | 15422 | 15463 | 15509 | 15555 |
| 10722 | 15290 | 15332 | 15381 | 15423 | 15464 | 15510 | 15556 |
| 12928 | 15291 | 15333 | 15382 | 15424 | 15465 | 15511 | 15557 |
| 14758 | 15292 | 15334 | 15383 | 15425 | 15466 | 15512 | 15558 |
| 15251 | 15293 | 15335 | 15384 | 15426 | 15467 | 15513 | 15559 |
| 15253 | 15294 | 15336 | 15385 | 15427 | 15468 | 15514 | 15560 |
| 15254 | 15295 | 15337 | 15386 | 15428 | 15469 | 15518 | 15561 |
| 15255 | 15296 | 15339 | 15387 | 15429 | 15470 | 15519 | 15562 |
| 15256 | 15297 | 15340 | 15388 | 15430 | 15471 | 15520 | 15563 |
| 15257 | 15298 | 15341 | 15389 | 15431 | 15472 | 15521 | 15564 |
| 15258 | 15299 | 15342 | 15390 | 15432 | 15473 | 15522 | 15565 |
| 15259 | 15300 | 15343 | 15391 | 15433 | 15474 | 15523 | 15566 |
| 15260 | 15301 | 15344 | 15392 | 15434 | 15475 | 15524 | 15567 |
| 15261 | 15302 | 15345 | 15394 | 15435 | 15476 | 15525 | 15569 |
| 15262 | 15303 | 15347 | 15395 | 15436 | 15477 | 15526 | 15570 |
| 15263 | 15304 | 15348 | 15396 | 15437 | 15478 | 15527 | 15572 |
| 15264 | 15305 | 15349 | 15397 | 15438 | 15479 | 15528 | 15573 |
| 15265 | 15306 | 15350 | 15398 | 15439 | 15480 | 15529 | 15574 |
| 15266 | 15307 | 15351 | 15399 | 15440 | 15481 | 15530 | 15575 |
| 15267 | 15308 | 15352 | 15400 | 15441 | 15483 | 15531 | 15576 |
| 15268 | 15309 | 15353 | 15401 | 15442 | 15484 | 15532 | 15577 |
| 15269 | 15310 | 15354 | 15402 | 15443 | 15485 | 15533 | 15581 |
| 15270 | 15311 | 15355 | 15403 | 15444 | 15486 | 15534 | 15582 |
| 15271 | 15312 | 15356 | 15404 | 15445 | 15487 | 15535 | 15583 |
| 15272 | 15313 | 15357 | 15405 | 15446 | 15488 | 15536 | 15585 |
| 15273 | 15314 | 15358 | 15406 | 15447 | 15489 | 15537 | 15587 |
| 15274 | 15315 | 15359 | 15407 | 15448 | 15490 | 15538 | 15588 |
| 15275 | 15316 | 15360 | 15408 | 15449 | 15495 | 15539 | 15589 |
| 15276 | 15318 | 15361 | 15409 | 15450 | 15496 | 15540 | 15591 |
| 15277 | 15319 | 15363 | 15410 | 15451 | 15497 | 15541 | 15592 |
| 15278 | 15320 | 15368 | 15411 | 15452 | 15498 | 15544 | 15593 |
| 15279 | 15321 | 15369 | 15412 | 15453 | 15499 | 15545 | 15594 |
| 15280 | 15322 | 15370 | 15413 | 15454 | 15500 | 15546 | 15595 |
| 15281 | 15323 | 15371 | 15414 | 15455 | 15501 | 15547 | 15596 |
| 15282 | 15324 | 15372 | 15415 | 15456 | 15502 | 15548 | 15597 |
| 15283 | 15325 | 15374 | 15416 | 15457 | 15503 | 15549 | 15598 |

Annex to FSCA MMS 2021-01.01
MEDUMAT Standard² serial numbers affected

| | | | | | |
|-------|-------|-------|-------|-------|-------|
| 15599 | 15647 | 15705 | 15913 | 16111 | 16182 |
| 15600 | 15648 | 15707 | 15916 | 16112 | 16183 |
| 15601 | 15649 | 15708 | 15917 | 16116 | 16184 |
| 15602 | 15650 | 15709 | 15918 | 16142 | 16185 |
| 15605 | 15651 | 15710 | 15919 | 16143 | 16186 |
| 15606 | 15652 | 15712 | 15920 | 16144 | 16187 |
| 15608 | 15653 | 15713 | 15921 | 16145 | 16188 |
| 15609 | 15654 | 15714 | 15922 | 16146 | 16189 |
| 15611 | 15655 | 15715 | 15923 | 16147 | 16190 |
| 15612 | 15657 | 15716 | 15927 | 16148 | 16191 |
| 15613 | 15658 | 15717 | 15929 | 16149 | 16192 |
| 15614 | 15659 | 15718 | 15945 | 16150 | 16193 |
| 15615 | 15662 | 15769 | 15947 | 16151 | 16194 |
| 15616 | 15664 | 15779 | 15950 | 16152 | 16195 |
| 15617 | 15665 | 15781 | 15951 | 16153 | 16196 |
| 15618 | 15666 | 15782 | 15952 | 16154 | 16197 |
| 15619 | 15667 | 15784 | 15953 | 16155 | 16198 |
| 15620 | 15668 | 15785 | 15955 | 16156 | 16199 |
| 15621 | 15669 | 15786 | 15956 | 16157 | 16200 |
| 15622 | 15670 | 15852 | 15966 | 16158 | 16201 |
| 15623 | 15671 | 15853 | 15968 | 16159 | 16202 |
| 15624 | 15672 | 15855 | 15969 | 16160 | 16203 |
| 15625 | 15673 | 15857 | 15970 | 16161 | 16204 |
| 15626 | 15674 | 15858 | 15972 | 16162 | 16205 |
| 15627 | 15675 | 15860 | 15973 | 16163 | 16206 |
| 15628 | 15676 | 15863 | 15974 | 16164 | 16207 |
| 15629 | 15677 | 15868 | 15984 | 16165 | 16208 |
| 15630 | 15678 | 15873 | 15985 | 16166 | 16209 |
| 15631 | 15679 | 15876 | 15986 | 16167 | 16210 |
| 15632 | 15680 | 15877 | 15987 | 16168 | 16211 |
| 15633 | 15681 | 15878 | 15988 | 16169 | 16212 |
| 15634 | 15682 | 15879 | 15990 | 16170 | 16213 |
| 15636 | 15683 | 15882 | 15991 | 16171 | 16214 |
| 15637 | 15689 | 15884 | 15992 | 16172 | 16215 |
| 15638 | 15690 | 15885 | 15993 | 16173 | |
| 15639 | 15691 | 15896 | 16045 | 16174 | |
| 15640 | 15698 | 15897 | 16046 | 16175 | |
| 15641 | 15699 | 15905 | 16047 | 16176 | |
| 15642 | 15700 | 15906 | 16048 | 16177 | |
| 15643 | 15701 | 15907 | 16085 | 16178 | |
| 15644 | 15702 | 15908 | 16088 | 16179 | |
| 15645 | 15703 | 15910 | 16108 | 16180 | |
| 15646 | 15704 | 15911 | 16109 | 16181 | |